K060564

FEB 7 2007

510(k) Summary

The following information is being provided in accordance with the requirements of 21 CFR 807.92

510(k) SUMMARY

Submitted By

AutoGenomics, Inc.
2251 Rutherford Road
Carlsbad, CA 92008, USA
Telephone: (760) 804-7378
FAX: (760) 804-7382

Contact Person: Evelyn Lopez
Director of Regulatory Affairs

Date Prepared: January 10, 2007

Device Name

Trade or Proprietary Name: INFINITI™ System Assay for Factor II & Factor V

Common or Usual Name: Factor II (Prothrombin) G20210G and Factor V Leiden G1691A Mutation Detection System

Classification Name: 21 CFR 864.7280 Factor V Leiden DNA mutation detection systems

Predicate Device

Roche Factor V Leiden Kit
Roche Factor II (Prothrombin) G20210A
Affymetrix GeneChip® Microarray Instrumentation System

Device Description

The INFINITI System Assay for Factor II & Factor V is an in vitro diagnostic device which utilizes proprietary film-based microarray technology combined with process automation, reagent management and software technology for the detection and genotyping of the Factor II (Prothrombin) G20210A mutation and the Factor V Leiden G1691A mutation from deoxyribonucleic acid (DNA) isolated from human whole peripheral blood samples.

The INFINITI System Assay for Factor II & Factor V is comprised of the BioFilmChip™ Microarray, the Intellipac™ Reagent Module, and the INFINITI Analyzer with the Qmatic™ Operating Software.

The BioFilmChip Microarray consists of a polyester film coated with proprietary multi-layer components designed for DNA analysis. The layers have been designed to provide a versatile surface to enhance test performance. There can be up to 240 spots

per microarray with each spot representing a different allele. The microarrays are designed to be assay specific.

The Intellipac Reagent Module which acts as a communication link contains up to eight reservoirs that house the test reagents and has an integrated memory chip. The assay protocol resides in this memory chip and upon request is loaded to the INFINITI Analyzer. Information such as expiration date of reagents, volume usage, time of use and operation parameters are archived in the memory chip and appear on the worklist (run report).

The INFINITI Analyzer is an instrument used for clinical multiplex systems intended to measure and sort multiple signals from a clinical sample. The INFINITI Analyzer is designed to measure fluorescence signals of labeled DNA target hybridized to BioFilmChip microarrays. The INFINITI Analyzer automates the Factor II and Factor V assays and integrates all the discrete processes of sample (PCR amplicon) handling, reagent management, hybridization, detection, and results analysis. The assays are processed automatically and read by the built-in confocal microscope. Results are analyzed and presented in numerical and graphical format.

The INFINITI Analyzer has two main components: pipetting and optics modules. A variety of electronic components inside the instrument are used for its operation. These include multiple stepper motors, heating and cooling devices, a barcode reader, a photomultiplier tube, and a camera all connected to USB ports

- Pipetting Module - The pipetting module performs all the operations related to dispensing and aspiration of reagent and processing the amplified sample to be dispensed on the microarray. When the sample has been processed and hybridized to the microarray, it is transferred to the optics module for scanning and reading.

- Optics Module - The optics module is a lightproof assembly comprised of a 3-axis stage; camera, lasers, and a photo multiplier tube (PMT). It is the enclosed casement into which the microarray is transported automatically prior to being processed on the stringency station. The optics' stage follows X-Y-Z motions that can be stepped at a very precise rate (2.0 micron per step). Using excitation wavelengths of a 760nm laser diode, the camera takes a 1.2x1.2mm picture for each registration spot of a fluorescent die. Analyses of these pictures allow the

location of three registration spots to be determined. With respect to the position of the three registration spots, coordinates of all the bio-spots can be located. While scanning, the stage moves along the Z-axis to focus the chip and the X and Y-axes to locate the individual spots on the microarray.

The INFINITI Analyzer hardware is controlled by the Qmatic™ operating software, which is installed with-in the on-board computer and utilizes a LCD screen display. The INFINITI Analyzer modules are controlled by multitasking real time software. The Qmatic™ operating software has a schedule manager that is capable of controlling all operations of the INFINITI Analyzer such as assay protocol, fluid handling, robotics, optical detection and result analysis. Results are available for review via the LCD screen. Management reports include results in numerical and graphical format. The operator can also print the displayed results in tabular form (printer not included with INFINITI Analyzer).

Intended Use

The INFINITI System Assay for Factor II & Factor V is an *in vitro* diagnostic device that consists of reagents and instrumentation which includes polymerase chain reaction (PCR) primers, hybridization matrices, a thermal cycler, an imager, and software for detection and genotyping of Factor II (Prothrombin) G20210A and Factor V Leiden G1691A point mutations in DNA obtained from human blood samples. The INFINITI System Assay for Factor II & Factor V is a qualitative assay for use in clinical laboratories upon prescription by the attending physician.

Indication for Use

The INFINITI System Assay for detection and genotyping of Factor II & Factor V is indicated for use as an aid to diagnosis in the evaluation of patients with suspected thrombophilia.

Substantial Equivalence

Comparison studies indicate that the INFINITI System Assay for Factor II & Factor V gives equivalent results to the FDA cleared Roche Factor II G20210A and Factor V Leiden Kits. 98.6% agreement between the two methods was observed when 208 samples were tested for the Factor II G20210A mutation. 100% agreement between the two methods was observed when 175 samples were tested for the Factor V Leiden G1691A mutation.

The INFINITI System Assay for Factor II & Factor V and the Roche Factor II and Roche Factor V Kits are based on the same principle: isolation of DNA from human blood sample, PCR amplification of the purified DNA, hybridization of the amplified

product, staining of the bound product, and signal detection using fluorescence. The INFINITI System Assay for Factor II & Factor V is a multiplex assay which detects Factor II and Factor V mutations simultaneously while the Roche Factor II and Factor V Kits are separate assays detecting each gene mutation.

Instrumentation used in the INFINITI System Assay for Factor II & Factor V is the INFINITI Analyzer which is similar in design and principle to the FDA cleared Affymetrix GeneChip® Microarray Instrumentation System. Both are multiplex systems designed to measure fluorescence signals of labeled targets hybridized to microarrays and perform hybridization, washing, scanning, and data analysis of microarray chips.

Instrument reproducibility data for the INFINITI Analyzer is comparable to those reported in the 510(k) Summary of the Affymetrix GeneChip Microarray Instrumentation System. See Performance Characteristics for the Reproducibility data for three INFINITI Analyzers tested using a standard microarray chip.

Performance Characteristics

The following are performance characteristics of the INFINITI System Assay for Factor II & Factor V:

Feature	*Performance*
Limit of Detection	1ng DNA/test
Assay Precision/Reproducibility	Chip-to-chip: Using the same sample and the same instrument, the assay was run using three chips from one lot of BioFilmChips five times. This was repeated two other times, each time using a different instrument. The CVs using average triplicate spots for each mutation ranged from 9 – 12% for wild-type present calls. All calls were 100% correct. Lot-to-lot: Three lots of BioFilmChip microarray were tested using the same instrument four times, each time using a different sample. Two-way ANOVA on the RFU readings did not detect lot-to-lot difference on three of the four test runs ($p > 0.05$), and detected lot-to-lot difference on one test run ($0.05 > p > 0.01$). Genotype calls were 100% correct. Day-to-day: Known genomic sample was assayed 12 times on each of three days using one instrument. The RFU signal %CV ranged from 1.35 to 14.87 on day1, 0.77 to 19.72 on day 2 and 0.41 to 21.2 on day

	3. Genotype calls were 100% correct.
Percent Agreement	(Based on Comparison studies between the INFINITI System Assay for Factor II & Factor V and the predicate (Roche Factor II and Factor V Kits) 98.6% for Factor II as compared with predicate 100.0% for Factor V as compared with predicate
Instrument Reproducibility	(see below*)
Reagent Stability	BioFilmChip Microarray: 90 days at RT (25-30 °C) Intellipac Reagent Module: 90 days at 4°C Amplification Mix: 90 days at 4°C
Interference	Results of the interference studies demonstrate that there is no interference with the INFINITI System Assay for Factor II & Factor V from 8mg/dL bilirubin, 70mg/dL cholesterol, and 1333v/dL heparin. No studies were conducted with oral anti-coagulants; therefore, no claims are made.
Sample Carry-over	No carry-over was detected when a series of 300ng of a wild type sample (FV-WT; FII-WT) was followed by 10ng of a positive sample (FV-WT; FII-M), followed by 300ng of a heterozygous sample (FV-H; FII-H), followed by a "No Template Control" or water, was run six times.

***Instrument Reproducibility**

- One DNA sample was analyzed using three different INFINITI Analyzers and one lot of BioFilmChips, five times (five runs).

  Intra-Instrument Reproducibility: The %CV using a single chip five times on a single instrument ranged from 0.9 to 28.3%CV. Genotype calls were 100% reproduced within each instrument

  Inter-Instrument Reproducibility: The %CV using a single chip five times on each of three instruments ranged from 0.5% to 12%CV. All genotype calls were 100% correct and reproducible.

- Three instruments were tested on three different days using a Standard (non-assay) Microarray Chip. For each instrument tested, each capture probe spot on

the Standard Microarray Chip was read 24 times, then averaged, and a %CV calculated for the spot. The following lists the ranges for the %CV for the three instruments tested.

Instrument	Ave %CV	%CV Range
1	4.03%	2.7-6.5%
2	3.99%	1.9-5.3%
3	3.24%	1.9-7.5%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUTOGENOMICS, INC.
C/O Evelyn Lopez
2251 Rutherford Road
Carlsbad, California 92008

MAY - 1 2007

Re: k060564
Trade/Device Name: INFINITI System Assay for Factor II & Factor V
Regulation Number: 21 CFR 864.7280
Regulation Name: Factor V Leiden DNA Mutation Detection System
Regulatory Class: Class II
Product Code: NPR, NPQ, NSU
Dated: March 2, 2006
Received: March 3, 2006

Dear Ms. Lopez:

This letter corrects our substantially equivalent letter of February 7, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060564

Device Name:

INFINITI™ System Assay for Factor II & Factor V

Indications for Use:

The INFINITI™ System Assay for Factor II & Factor V is an *in vitro* diagnostic device that consists of reagents and instrumentation which includes polymerase chain reaction (PCR) primers, hybridization matrices, a thermal cycler, an imager, and software for detection and genotyping of Factor II (Prothrombin) G20210A and Factor V Leiden G1691A point mutations in DNA obtained from human blood samples. The INFINITI™ System Assay for Factor II & Factor V is a qualitative assay for use in clinical laboratories upon prescription by the attending physician.

The INFINITI™ System Assay for detection and genotyping of Factor II & Factor V is indicated for use as an aid to diagnosis in the evaluation of patients with suspected thrombophilia.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Division Sign-Off

Concurrence of CDRH, Office of Device Evaluation (ODE)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K060564